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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,568	02/18/2004	Edouard Koullick	539.5005.1	9297

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
09/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,568	KOULLICK ET AL.	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,16-28,30-45,48-63,66 and 67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,16-28,30-45,48-63,66 and 67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 July 2008 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 2, 6, 11, 12, 13, 16-19, 23, 28, 30-33, 37, 42-45, 48-51, 55, 60-63, 66, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,195,608 to Burnett in view of US 6,656,50 to Wu et al.

In the specification and figures, Burnett discloses the apparatus as claimed by applicant. With regard to claims 1,18, 32, 50 Burnett discloses an implantable fluid management system that may be implanted within a patient comprising an elongated conduit or cannula or tube 11 with a lumen therethrough, a proximal end with at least one opening or a plurality of perforations at the intake end (see column 3, lines 10-20).

The tube comprises an outflow end that discharges bodily fluids to another location within the body (see, generally, columns 1-2, FIG 16C). The conduit comprises one or more occlusion-resistant materials that may be integrated within or coated upon the surfaces of the system, which include the lumen of the tube 11 (see column 7, lines 38-65).

Burnett fails to disclose that the occlusion resistant materials are distributed in separate insertable agent delivery devices selected from the group comprising spheres, plugs, seeds, rods, or combinations thereof. Applicant claims that the agent delivery device may comprise one or more separate elements. Wu discloses an implantable medical device that incorporates polymer-based drug eluting microparticles of various shapes (including spheres) in order to allow site-specific treatment within various portions of the implantable device (see column 2, lines 25-65, column 3, lines 29-31, 39-41, column 4, lines 20-25, 64-67, column 5, lines 10-30).Wu specifically discloses that the medical device formed and dipped in a solution such that the entire structure, both interior and exterior, are coated. As such, the device disclosed by Wu is capable of releasing drugs form the interior of the conduit as claimed by applicant. Since Wu discloses that the device is coated with a layer of microparticles, it is the position of the Examiner that this layer, added after the manufacture of the implantable device, comprises a "separate" agent delivery device, since it is applied separately after the construction of the device and comprise discrete, or "separate" microparticle delivery devices.

With regard to Applicant's recitation of "insertable" agent delivery devices, Applicant has not provided any special definition of "insertable" or "insert" in the specification, and it is the position of the Examiner that such an insert should be given its broadest reasonable interpretation, which includes actions such as "to put in" or to "put into action." See Merriam Webster's Collegiate Dictionary, 10th Ed, 2001. It is the position of the Examiner that Wu's drug eluting microparticles further comprise "insertable" delivery devices that are *capable* of being inserted, or put in the cannula in order to elute drugs therefrom.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add drug eluting microspheres as disclosed by Wu to the drug eluting shunt suggested by Burnett, in order to provide site-specific treatment within various portions of the implantable device, as taught by Wu.

Furthermore, the prior art demonstrates that all of the elements are known in the art. One of ordinary skill in the art could have combined the known elements according to known means, yielding only the predictable result of an implantable shunt comprising separate drug eluting delivery agents, suggesting the limitations of the claim.

With regard to claims 2, 19, and 33, Burnett discloses that the shunt may incorporate a ball valve 4 (see FIGS 5A, 5B, 5C).

With regard to claims 6, 23, 37, 51, 55, Burnett discloses that the occlusion-resistant material may comprise antibiotics (see column 7, lines 38-65).

With regard to claims 11, 42, and 60, Wu specifically discloses that the medical device is formed and dipped in a solution such that the entire structure, both interior and

exterior, are uniformly coated with the medicament which may comprise an occlusion-resistant material.

With regard to claims 12, 13, 16, 28, 30, 43, 45, 48, 61, 63, and 66, Wu discloses that only select portions of the medical device are coated with one or more polymer matrices, indicating that the applied medicament is distributed only in select drug eluting regions (that is, non-uniformly in amounts from 0% to 100%), and different polymer matrices (which corresponds to applicant's "different agent delivery devices" of claim 28) loaded with various drugs (corresponding to claim 45) may be used in different regions of the device (see column 2, lines 50-56).

With regard to claims 17 and 31, Applicant claims the manner in which the claimed device is intended to operate. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. Wu specifically discloses that the nature of the polymer used to load the medicament onto the medical device may be used to control the rate of release of the medicament from the matrix, indicating that the device suggested by the prior art is capable of performing as claimed by applicant, meeting the limitations of the claims (see Wu column 2, lines 60-67).

With regard to claims 44 and 62, Burnett discloses that in an embodiment, a pump (which may act as a barrier to fluid movement, corresponding to a valve), may incorporate medicaments that include occlusion-resistant properties, meeting the limitations of the claim (see column 12, lines 13-30)

With regard to claims 49 and 67, Wu specifically discloses that the nature of the polymer used to load the medicament onto the medical device may be used to control the rate of release of the medicament from the matrix, indicating that the device disclosed by Wu allows for controlled drug release rate (see Wu column 2, lines 60-67).

4. Claims 3-5, 20-22, 34-36, 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,195,608 to Burnett in view of US 6,656,50 to Wu et al, further in view of US 5,928,182 to Kraus.

In the specification and figures, the prior art suggests the apparatus substantially as claimed by applicant (see rejection above) with the exception of the composition of the implantable shunt. Kraus discloses a shunt comprising a conduit with inflow and outflow ends (see FIG 6A) that comprises a valve to control fluid flow and that may be made of silicone or polyurethane in order to enhance biocompatibility (see column 3, lines 15-30, column 6, lines 45-57). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to form the shunt suggested by the prior art of silicone or polyurethane as disclosed by Kraus in order to enhance biocompatibility of the shunt suggested by the prior art.

5. Claims 7-10, 24-27, 38-41, and 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,195,608 to Burnett in view of US 6,656,50 to Wu et al, further in view of US 2005/0208095 A1 to Hunter et al.

In the specification and figures, the prior art suggests the device and method substantially as claimed by applicant (see rejection above) with the exception of incorporating mycophenolic acid as a therapeutic agent within the shunt. With regard to claims 7,8, 9, 24-26, 38-40, and 56-58, Hunter discloses a method of treating patients with various conditions by providing an implantable medical device comprising a therapeutic agent into a patient and allowing the therapeutic agent to elute into the patient (see, generally, paragraph 0014). In an embodiment, the therapeutic material may comprise mycophenolic acid and other agents in order to inhibit fibrosis (see paragraph 0223). It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the shunt suggested by the prior art with the therapeutic agent disclosed by Hunter in order to provide the desired therapeutic result and inhibit fibrosis, as taught by Hunter.

With regard to applicant's claims 10, 27, 41, and 59, drawn to a "combination" of mycophenolic acid and another agent, applicant fails to specify the amounts of the combination. Accordingly, Hunter's disclosed mixture, since Applicant provides no specific amounts, suggests the invention claimed by Applicant.

Response to Arguments

6. Applicant's amendments and arguments dated 17 July 2008 have been entered and fully considered.

7. Applicant argues that the cited art does not teach separate agent delivery devices that are inserted within the lumen of the claimed shunt or cannula. The Examiner respectfully disagrees. Wu specifically teaches an implantable medical device that is separately coated with a matrix that may comprise a medicament. It is the position of the Examiner that since the polymer matrix with medicament is not formed integrally within the structure of the medical device, it comprises a "separate" agent delivery device as claimed by applicant. Furthermore, the spheres themselves represent discrete, or separate delivery agents.

With regard to Applicant's recitation of "insertable" agent delivery devices contained within the lumen, Applicant has not provided any special definition of "insertable" or "insert" in the specification, and it is the position of the Examiner that such an insert should be given its broadest reasonable interpretation, which includes actions such as "to put in" or to "put into action." See Merriam Webster's Collegiate Dictionary, 10th Ed, 2001. It is the position of the Examiner that Wu's drug eluting microparticles, that are located on the walls that surround the lumen of the shunt, comprise "insertable" delivery devices that are *capable* of being inserted, or put in the cannula facing the lumen (thereby contained within the lumen), in order to elute drugs therefrom.

8. Applicant argues that the Kraus and Hunter fail to cure the deficiencies of the prior art. However, the Examiner relies on the Kraus and Hunter references to teach only the preferred materials of the suggested device. The instantly pending claims are held by the Examiner to be unpatentable over the prior art of record.

Conclusion

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
8 September 2008